

Appl. No. : 10/719,532  
Filed : November 21, 2003

### **REMARKS**

The claim amendments and remarks herein are responsive to the Office Action dated August 14, 2007. Claims 1-2 and 7-24 are pending. Claims 7, 9-10, and 13-24 are withdrawn. Claims 1-2, 8, and 11-12 are currently under examination.

#### **Claim Objections**

The Office objects to Claim 1 because of the following informality: The group consisting of one or more of the following is improper Markush language. Claim 1 is amended to recite, *inter alia*, "wherein said helminth-based antigen comprises a protein obtained from a helminth selected from the group consisting of *Capillaria hepatica* and *Dicrocoelium dendriticum*, . . ."

Accordingly, Applicant respectfully requests withdrawal of the claim objection.

#### **Claim Rejections Under 35 U.S.C. § 112 – first paragraph: Enablement**

The Office rejects Claims 1-2, 8, and 11-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicant has amended Claim 1.

The Office states that there is "no data to enable the claims." Applicant believes that the Examiner's request for data was based on the breadth of the previously presented claims. In view of the amendments identified above, Applicant asserts that the specification provides ample support for the claims. However, any subsequent argument by the Examiner that data is required to support the amended claims would, respectfully, be unfounded. It is well-established that an applicant is not required to submit data to establish enablement. For example, in *Ex Parte Kyle*, the Board of Patent Appeals and Interferences reversed the Examiner's rejection of claims and explained:

The examiner has not explained why the specification's straightforward protocols for synthesizing, identifying and using bradykinin antagonists, together with what was known in the art at the time of the invention, does not satisfy the enablement requirement of 35 U.S.C. § 112.

Finally, to the extent that the examiner requires an assurance of certainty ("[t]here is insufficient bioassay data provided ... which teaches that all of the possible Bk analogs would be effective as antagonist," (Examiner's Answer, page 3)) to demonstrate enablement, we note that

Appl. No. : 10/719,532  
Filed : November 21, 2003

no legal authority has been cited in support of this requirement. On the contrary, a requirement for certainty would be incompatible with any experimentation at all. Accordingly, the rejection of claims 1, 2, 4 and 5 under 35 U.S.C. § 112, first paragraph is reversed.

*Ex Parte Kyle*, 2000 WL 35451360, \*4 (Bd.Pat.App. & Interf.). See also *Carter-Wallace, Inc. v. Riverton Laboratories, Inc.*, 433 F.2d 1034, 1037-1038 (2d Cir. 1970) (emphasizing that "submission of test information to the Patent Office in support of the claims made in an application is not required, unless the asserted utility of a compound is not believable on its face to persons skilled in the art in view of the contemporary knowledge in the art."). Here, the asserted utility of the claims should not be questioned. Indeed, the Examiner has not rejected any of the claims under § 101 for lack of utility. Moreover, in light of the Examiner's reliance upon prior art that allegedly anticipates or obviates Applicant's claimed invention, it would be inconsistent for the Examiner to later allege that the asserted utility of a helminthic antigen for treating allergies or asthma is not believable to persons skilled in the art.

In view of the above amendments and remarks, the Applicant respectfully requests that the Examiner withdraw the written description and enablement rejections.

**Claim Rejections Under 35 U.S.C. § 102(b): Rejections Over De Macedo et al.; Ferreira et al.; and U.S. Patent No. 5,996,758**

The Office rejected Claims 1-2 and 11-12 under 35 U.S.C. § 102(b) as being anticipated by *De Macedo et al.* (1980). The Office also rejected Claims 1-2 and 11-12 under § 102(b) over *Ferreira et al.* (1994). The Office also rejected Claims 1-2, 8, and 11-12 under § 102(b) over U.S. Patent No. 5,996,758.

The cited art fails to anticipate amended Claim 1. The cited art fails to teach or suggest a protein obtained from *Capillaria hepatica* or *Dicrocoelium dendriticum*, as recited in amended Claim 1. Further, amended Claim 1 recites: *wherein said helminth-based antigen increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens.* There is simply no teaching, suggestion, or motivation in the cited art to use a helminth-based antigen that increases IgE levels in order to treat allergies or asthma.

Appl. No. : 10/719,532  
Filed : November 21, 2003

Accordingly, Claim 1 is patentable over the cited art. The claims which depend from Claim 1 are also allowable because they depend from an allowable base claim and/or because they recite independently patentable features. Thus, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 102(b).

**Claim Rejections Under 35 U.S.C. § 102(b): Rejection Over Gonzalez-Lanza et al.**

The Office rejected Claims 1-2 and 11-12 under 35 U.S.C. § 102(b) as being anticipated by *Gonzalez-Lanza et al.*

As amended, Claim 1 recites: *wherein said helminth-based antigen increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens.* There is simply no teaching, suggestion, or motivation in *Gonzalez-Lanza et al.* to use a helminth-based antigen that increases IgE levels as recited in amended Claim 1 in order to treat allergies or asthma.

Accordingly, Claim 1 is patentable over *Gonzalez-Lanza et al.* The claims which depend from Claim 1 are also allowable because they depend from an allowable base claim and/or because they recite independently patentable features. Thus, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 102(b).

**Claim Rejections Under 35 U.S.C. § 102(a)**

The Office rejected Claims 1-2, 8 and 11-12 under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent 6,207,158.

U.S. Patent 6,207,158 fails to anticipate Claim 1. The cited art fails to teach or suggest the use of a helminth-based antigen that increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens.

Accordingly, Claim 1 is patentable over U.S. Patent 6,207,158. The claims which depend from Claim 1 are also allowable because they depend from an allowable base claim and/or because they recite independently patentable features. Thus,

Appl. No. : 10/719,532  
Filed : November 21, 2003

Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 102(a).

**Reservation of Rights**

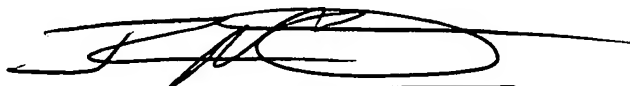
Claims canceled in this application are done so without prejudice. Moreover, although the present communication may include alterations to the application or claims, Applicant is not conceding that the previously pending claims are not patentable over the art of record. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to later pursue any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

**Appl. No.** : 10/719,532  
**Filed** : November 21, 2003

Should the Office believe anything further is required to place the application in condition for allowance the Examiner is invited to contact Applicant's representative at the telephone number listed below.

The Director is hereby authorized to charge any deficiency or credit any overpayment to deposit account number 03-2469. Moreover, if the deposit account contains insufficient funds, the Director is hereby invited to contact the undersigned to arrange payment.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Coulby', written over a horizontal line.

Dated: May 28, 2008

JOHN N. COULBY, Reg. No. 43,565  
KELLEY DRYE & WARREN, LLP  
3050 K Street, N.W., Suite 400  
Washington, D.C. 20007  
(202) 342-8400